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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,717	09/01/2000	Gabriel Villafane	EGYP 3.0-008	5779

530            7590            10/22/2002  
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[REDACTED] EXAMINER

COOK, REBECCA

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1614

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/653,717	VILLAFANE ET AL.
	Examiner Rebecca Cook	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 06 June 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 10-16, 18--28, 30-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10-16, 18-28 and 30-49 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                                  |                                                                              |
|------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                             | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11, p.2</u> | 6) <input type="checkbox"/> Other: _____ .                                   |

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The Draftsman approved the drawings.

Claims 10-16, 18-28, 30-49 are present for examination.

Claims 10, 39-41, 43-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support is seen in the specification for the rate of claim 39. Applicants' argument regarding Example 1 and the patients weight is not persuasive, since this is not disclosed in the specification. It is not seen where support is found for the recitations of the other claims, and applicants have not pointed out where it may be found.

Claims 10-16, 18-27, 44-46, 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons given in Paper No. 12 and further as set forth below.

*No amend to recite grad incr.*  
The word "progressive" in claims 10 and 44 is confusing and it is not seen where it is defined in the specification.

*Canc.*  
The word "includes" in claim 11 is confusing and it is not clear what else the second component intends to comprise. Furthermore, said claim does not limit claim 10 from which it depends, because the second component in claim 10 is required to comprise L-Dopa.

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01C  
Applicants argument regarding the word "improving" has been considered but is not persuasive in view of the use of the word "restoring" in the specification on page 3, line 11.

In view of applicants' arguments and amendments to the claims the remaining earlier rejections under 35 U.S.C. 112, paragraph two are withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:\

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Domino et al or applicants' admissions for the reasons given in Paper No. 12.

Applicants' argument that Domino worked with monkeys rather than human subjects and that they had induced PD is not persuasive. Only claim 16 recites that the subject of the instant method is a human. Furthermore, animal models using induced conditions are well established in the scientific and medical community as an indicator of the usefulness of a method of treatment. Applicants' argument regarding the duration of treatment is not persuasive. It is well known that chronic disease requires continuous treatment to manage symptoms.

Applicants' argument that the instant drug combinations are not suggested by Domino is not persuasive. Domino suggests studying the effect of other dopaminergic agonists, rendering the instantly recited dopaminergic agonists obvious.

Applicants' argument that a sub-active dose of L-Dopa is useful in combination with nicotine to treat PD is not persuasive, since this is not claimed. Applicants' argument that new claims 39-49 are patentable over Domino is not persuasive, since

once a method and composition is known, specific routes of administration and dosages are within the skill of the artisan.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*Rebecca Cook*  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200

October 21, 2002